Supreme Court of the United States

OCTOBER TERM, 1948.

No. 30.

LELORD KORDEL,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

BRIEF FOR THE APPELLANT.

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Appellant,

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CITATIONS

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OPINIONS BELOW

The opinion of the circuit court of appeals (R. 461-467) is reported at 164 F. 2d 913. The opinion of the district court is reported (R. 440-443) at 66 F. Supp. 538.

JURISDICTION

The judgment of the circuit court of appeals for the seventh circuit affirming the conviction of petitioner was entered on November 6, 1947 (R. 468). A petition for rehearing, timely made, was denied on January 22, 1948 (R. 474). Appellant's time to file a petition for a writ was extended to March 15, 1948, by order of Mr. Justice Murphy (R. 480). The petition was filed March 5, 1948. An order allowing certiorari was filed April 19, 1948 (R. 480). The jurisdiction of this Court is invoked under section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925, c. 229, §1, 43 Stat. 938 [U. S. C., Title 28, §347(a)].

STATEMENT OF THE CASE

This proceeding was initiated by the filing of three criminal informations, comprising twenty counts, by the United States in the Eastern Division of the District Court of the United States for the Northern District of Illinois as causes Nos. 45 CR 488, 45 CR 490, and 46 CR 1 (R. 3-9, 19-37, 49-106). The informations charged generally that certain foods and drugs when introduced and delivered for introduction into interstate commerce were accompanied by certain circulars, which were alleged to be false or misleading, and such foods and drugs were, by reason thereof, *then and there* misbranded. Similarly, the only charge made against appellant in said informations was the violation of section 301(a) of the Federal Food, Drug, and Cosmetic Act [U. S. C., Title 21, §331(a)] which reads as follows: "The following acts and the causing thereof are hereby prohibited: *(a)* The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. * * *"

It is also material to note that appellant was prosecuted by information and not by indictment.

The Separate Shipments of Food or Drug and Allegedly Misbranded Circular

In the counts of the informations mentioned in the footnote[1] the booklets, pamphlets, and circulars in no instance accompanied the product charged with being misbranded *at the time it was introduced into interstate commerce.* In addition, the products and printed matter were shipped from two different cities in Illinois. The time separating the shipment of the "misbranded" articles and the printed matter allegedly causing their misbranding ranged as fol-

[1] Information 45 CR 488, Information 45 CR 490, Counts 5 and 6, and Information 46 CR 1, all counts.

lows: 2, 36, 41, 58, 71, 105, 188, and 561 days (see Fig. 1, page 4 this Brief). For example, in one case (Information 45 CR 490, Count 6) the article was shipped on July 10, 1942, and the printed matter over 18 months later on January 18, 1944 (R. 35-38).

No evidence was introduced by the Government that such printing matter ever accompanied the product in a physical sense, or that any consumer received the printed matter or relied, either in making the purchase or in using the product, upon the printed matter so shipped. On the contrary, the products were generally of the nature of familiar vitamins, minerals and herbs. Where directions for use were necessary they were stated on the label (*cf.* R. 35-36, BOLAX LAXATIVE TABLETS label).

CIRCULARS AND MAGAZINES INTENDED FOR MAILING BY DEALER

Government Exhibits 8 (R. 142) and 24 (R. 158)[2] bore post-office mailing permit indicia, together with space for addressing. The former was shipped 36 days *after* the articles with which they are now connected; the latter six months *before* the products. The sole purpose of their shipment to the dealers was for mailing to the dealers' lists (R. 145, 146, 161, 167, 335). Most, if not all, were actually mailed (R. 146, 161, 167) or addressed for mailing when seized (R. 147), and, in both instances, the printed matter was generally held for addressing and mailing separate from the retail portions of the stores (R. 150, 162, 166). The United States attorney at the trial pointed out that distribution of this printed matter constituted a violation of law unless the postal insignia were blocked out (R. 148). This had not been done by, or at the direction of, appellant.

[2] The so-called *Gotu Kola* circular and the magazine entitled "Health Today Spring 1945," involved in Information 45 CR 488 and Information 46 CR 1, Counts 1 to 12, inclusive.

FIG. I—SUMMARY OF DATES OF SHIPMENTS OF ARTICLE AND "ACCOMPANYING LABELING"

Information	*Count No.*	*Date of Shipment of article*	*Date of shipment of printed matter*	*Days separating shipments*
45 CR 488		Nov. 6, 1943	May 6, 1943	188
45 CR 490	5	Jan. 20, 1944	Jan. 18, 1944	2
	6	July 10, 1942	Jan. 18, 1944	561
46 CR 1	1	Jan. 22, 1945	Feb. 27, 1945	36
	2	Jan. 22, 1945	Feb. 27, 1945*	36
	3	Jan. 22, 1945	Feb. 27, 1945	36
	4	Jan. 22, 1945	Feb. 27, 1945*	36
			Nov. 13, 1944**	71
	5	Jan. 22, 1945	Feb. 27, 1945*	36
			Nov. 13, 1944**	71
	6	Jan. 22, 1945	Nov. 13, 1944**	71
	7	Jan. 22, 1945	Feb. 27, 1945	36
	8	Jan. 22, 1945	Feb. 27, 1945*	36
	9	Jan. 22, 1945	Feb. 27, 1945	36
	10	Jan. 22, 1945	Feb. 27, 1945*	36
			Nov. 13, 1944**	71
			Oct. 9, 1944 to	105
			Nov. 25, 1944***	58
	11	Jan. 22, 1945	Feb. 27, 1945	36
	12	Jan. 22, 1945	Feb. 27, 1945	36
	13	Oct. 16, 1944	Sept. 5, 1944	41

* *Health Today Spring 1945*
** *Arthritis*
*** *The Art of Relaxation*

The Booklets Priced for Sale and Independently Sold

Government's Exhibits 8A, 8B, and 8C (R. 142) are three so-called "Health Books," each plainly marked with the price thereof. All were sold by dealers independently of the sale of the products with which they are here connected; none was distributed to customers as advertising or labeling matter (R. 132, 146).

The Conviction and Subsequent Proceedings

Upon these facts the trial court filed its opinion on June 27, 1946 (R. 440-443, also reported in 66 F. Supp. 538), and judgment and sentence were pronounced on the same date.

An appeal was taken to the circuit court of appeals for the seventh circuit. Upon appeal, in the court below, appellant contended: (1) That booklets, pamphlets, and circulars, not physically accompanying a food or drug in interstate commerce, are not "labeling" as defined in, and hence are not subject to, the Federal Food, Drug, and Cosmetic Act; (2) that the booklets, pamphlets, and circulars did not accompany the articles when they were introduced or offered for introduction into interstate commerce as charged; (3) that Government's Exhibits 8 and 24 did not "accompany" any articles at any time in interstate commerce, or thereafter, but were intended for, and actually used as "mailing pieces"; (4) that a book or booklet, priced for sale and actually sold, does not "accompany" any article in interstate commerce, and does not constitute "labeling"; (5) that the trial court erred in holding that reference to a food, with honest and truthful qualifications as to its use and purposes, constituted an actionable representation that the food was a drug offered for the cure, mitigation, treatment, and prevention of

arthritis; (6) that the trial court erred in refusing to place a strict construction on the penal sections of the statute; (7) that the trial court erred in holding that the weight of proof requisite to conviction under the criminal provisions of the statute was similar to that required in the civil trial of a condemnation proceeding thereunder; (8) that in violation of his constitutional rights, defendant was prosecuted by information instead of by indictment; and (9) that the so-called "labeling" decisions relied upon by the trial court were not in point.

These contentions were rejected (R. 461-467). The circuit court conceded that "no charge of falsehood is made as to the principal labels printed on the packages in which each is contained" but claimed that the test of whether printed matter "accompanies" an article is "not of physical contiguity but of textual relationship." It also found that misbranding takes places under the Act if "ignorant and gullible persons are likely to rely upon them instead of seeking professional advice." It implied that there is no distinction between "advertisements" and "labeling" under the Federal Food, Drug, and Cosmetic Act. Appellant's petition for rehearing was denied on January 22, 1948.

Other Facts

Although other pertinent details will appear in the Argument, it seems advisable at this point to emphasize two additional aspects of the facts. Both lower court decisions seem actuated in large part by the fact that appellant is alleged to be "a self-styled authority on nutrition and vitamins" (R. 462). The courts appear more concerned with the appellant's practices as a "health food" lecturer and writer than in his constitutional rights as an American

citizen. The issue in this case is not whether appellant is or is not an "authority"; rather the important question presented is whether, as charged, appellant introduced into interstate commerce foods or drugs that were "then and there" misbranded. Both the trial court and the circuit court of appeals in their decisions ignored this charge and based their findings on what were undoubtedly considered broad considerations of social policy and significance.

This runs counter to the most elementary principles of American jurisprudence. The character of the accused is not, generally speaking, an issue in a criminal case (*Greer* v. *United States*, 245 U. S. 559), nor should the irrelevant nature of the product itself affect the determination of a legal proposition. In *United States* v. *Johnson*, 221 U. S. 488, the fact that the patent medicine before the court was *Dr. Johnson's Mild Combination Treatment for Cancer* did not swerve this Court from, in substance, emasculating the Food and Drugs Act of 1906 when legal principles so warranted.

Similarly, if previous conduct prevails, appellee will attempt to sway this Court by isolated quotations from the testimony of the expert medical witnesses (*cf.* Memorandum for the United States on Petition for Writ of Certiorari, pp. 5-6). However, since it is appellant's contention that the real merits of this appeal lie in other directions, only one example illustrative of the nature of the atmosphere prevailing at the trial and the nature of the medical testimony will be given.

Government's Exhibit 1 (*Arthritis* booklet) (R. 132) contains a number of footnotes which the prosecution has distorted to imply that the articles designated therein were offered for the cure, mitigation, treatment, *and* prevention of arthritis (Information 45 CR 490, Counts 1, 2, 5, and 6, and Information 46 CR 1, Counts, 4, 5, 6, and 13. R. 19-28,

29, 34-35, 36-37, 66-72, 76-77, 80, 106). The reckless nature of these charges at once becomes evident when the exhibit itself is examined. Thus, on page 5, its text suggests that carbohydrates, spicy foods, alcohol, and tobacco be eschewed in arthritis. As a footnote to the remark regarding coffee, the statement is made:

> "Instead of coffee, drink Lelord Kordel's Sarsaparilla Tea. • • • If you *must* drink coffee—and arthritics shouldn't!—learn to drink it without sugar or cream, and add a few drops of lemon juice to it in order to neutralize harmful elements."

The informations charge that this innocuous statement about a beverage, suggested in lieu of coffee (R. 29):

> "• • • represented and suggested and created the impression in the mind of the reader that said *drug* when taken alone, or in combination with other drugs mentioned in said booklet • • • *would be effective in the cure, mitigation, treatment, and prevention of arthritis* • • • (Italics supplied.)

The trial court, moreover, permitted the expert medical witness to render an opinion as to whether sarsaparilla tea was effective in the *cure* of arthritis (R. 308-9). The witness, it is interesting to note, failed to answer this question, but departed on a discourse relative to uric acid, implying that *another* statement in the booklet, regarding the action of coffee, was no longer accepted (R. 309). Similar footnotes, found on subsequent pages of the exhibit, are:

> "For a reliable source of calcium-phosphorous-Vitamin D, try MINERALS-PLUS—which contains the two minerals *plus* 17 others in addition to Vitamin D and Chlorophyll."
>
> "FERO-B-FLEX is an excellent iron-rich B-Complex supplement."

"BoLAX is recommended when you feel the need for a mild, yet not harsh laxative. Insist on getting BoLAX, and *refuse* substitutes!

In each instance the witness was permitted, over objection, to discuss these products in the light of their effectiveness in the "cure, mitigation, treatment or prevention of arthritis, and specially rheumatoid arthritis" (R. 312-320). No evidence was adduced that the statements, in themselves, were false or misleading.

B

STATEMENT OF THE JURISDICTION OF THIS COURT

(1) STATUTORY PROVISION BELIEVED TO SUSTAIN THE JURISDICTION.

The jurisdiction of this Court is invoked under section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925, c. 229, § 1, 43 Stat. 938 [U. S. C., Title 28, § 347(a)].

(2) THE DATE OF THE JUDGMENT TO BE REVIEWED.

The judgment of the circuit court of appeals for the seventh circuit affirming the conviction of appellant was entered on November 6, 1947 (R. 468). A petition for rehearing was denied on January 22, 1947 (R. 474). A petition for a writ of certiorari to this Court was granted on April 19, 1948 (R. 480).

(3) STATEMENT OF THE NATURE OF THE CASE AND THE RULINGS OF THE CIRCUIT COURT OF APPEALS BRINGING THE CASE WITHIN THE JURISDICTION OF THIS COURT.

The nature of the case (prosecutions under the Federal Food, Drug, and Cosmetic Act) has been heretofore stated.

The circuit court of appeal's rulings have heretofore been stated in part; it rejected appellant's contentions (R. 461). Each of such rulings is reviewable by this Court under the appropriate statutory provisions noted.

(4) Cases Believed to Sustain the Jurisdiction of this Court.

This Court is vested with jurisdiction under the statutory provisions heretofore specified. The cases submitted by appellant as the basis for the exercise of such jurisdiction, to review the judgment below, are cited hereafter.

C

SPECIFICATION OF ASSIGNED ERRORS

(1) The lower courts erred in finding and holding that printed matter shipped from two to 561 days apart from the food or drug which it merely mentions by name is "labeling" accompanying such article.

(2) The lower courts erred in finding and holding that printed matter shipped many months after the article is introduced into interstate commerce misbrands the article "when introduced and delivered for introduction into interstate commerce."

(3) The lower courts erred in finding and holding that printed matter, shipped for distribution by mail by the local dealer, accompanies an article at the time it is "introduced and delivered for introduction into interstate commerce."

(4) The lower courts erred in finding and holding that books, priced for sale and sold independently of an article, accompany such article at the time of the latter's shipment.

(5) The lower courts erred in finding and holding that the penal provisions of the Federal Food, Drug, and Cosmetic Act are not entitled to a strict construction.

(6) The lower court erred in finding and holding that the burden of proof requisite to conviction under the criminal provisions of such statute is similar to that required in a civil proceeding.

(7) The lower court erred in finding and holding that appellant was properly prosecuted by information instead of indictment.

(8) The circuit court of appeals erred in finding and holding that labeling is false or misleading if the public is likely to rely upon statements contained therein instead of seeking professional advice.

SUMMARY OF ARGUMENT

1

The informations charged that appellant, on or about a specified date:

> "• • • *then and there* in violation of the Act of Congress • • • unlawfully introduce and deliver for introduction into interstate commerce from • • • to • • • a certain consignment, to wit, a carton of [*the article involved, also identified by its label*].

The informations go on to allege:

> "That displayed upon written, printed, and graphic matter *accompanying said drug when introduced and delivered for introduction into interstate, commerce, as aforesaid,* namely, upon a number of printed circulars • • •, which said circulars the

defendant [shipped or caused to be shipped by] to * * * on [*a date other than the date of the shipment of the consignment*] were among other things * * * [*statement of claims*].

The informations continue:

"That said drug when introduced and delivered for introduction into interstate commerce and when caused to be introduced and delivered for introduction into interstate commerce was *then and there* misbranded * * *." (Italics supplied for emphasis. R. 3, 4, 8; 33, 34; 35, 36, 49-106.)

Appellant has been convicted of these crimes on evidence disclosing that:

1. The printed matter containing the alleged false or misleading claims in no instance accompanied the product charged with being misbranded at the time it was introduced into interstate commerce, but on the contrary was shipped from different cities in Illinois from 2 to 561 days apart from the shipment of the articles.[3]

2. Two of the circulars were not only shipped from one to six months apart from the articles with which they are now connected but also bore a post-office mailing permit indicia, together with space for addressing, and were intended for, and actually mailed or addressed for mailing, for that purpose being kept separate from the retail portions of the stores;[4]

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[3] Information 45 CR 488, Information 45 CR 490, Counts 5 and 6, and Information 46 CR 1, all counts, where the booklets, pamphlets, and circulars were introduced into, and transported in, interstate commerce wholly apart from the alleged misbranded articles involved.

[4] Information 45 CR 488 and Information 46 CR 1, Counts 1 to 12, inclusive.

3. The three paper-bound "health" books involved were each plainly marked as to its price and were sold by the dealer independently of the display or sale of the allegedly misbranded articles made reference to only by name in their pages.[5]

The trial court found that each of the foregoing circulars, pamphlets and books constituted "labeling," as that term is defined in the Federal Food, Drug, and Cosmetic Act (R. 443). The circuit court of appeals affirmed this conclusion, invoking the novel and far-reaching concept that "the test [of accompliment] is not of physical contiguity but of textual relationship" (R. 464).

The argument presented here will demonstrate that both courts so erred in at least two different respects:

(1) In holding that printed matter not physically accompanying a specific article at any point in interstate commerce is "labeling" as defined in the Federal Food, Drug, and Cosmetic Act; and

(2) Assuming that such printed matter does constitute "labeling;" in finding appellant guilty of section 301(a) [U. S. C., Title 21, §331(a)] which is limited to the prohibition of "the introduction or delivery for introduction into interstate commerce of any food, drug, • • • *that is* • • • *misbranded.*" (Italics supplied.)

2

Appellant was entitled to a strict construction of the Act with proof of violation, if any, beyond a reasonable doubt.

3

In violation of his constitutional rights, appellant was prosecuted by information instead of by indictment.

[5] Information 45 CR 490, all counts, and Information 46 CR 1, Counts 2, 4, 5, 6, 8, 10, and 13.

4

The circuit court erred in its definition of false or misleading branding.

ARGUMENT

I.

THE LOWER COURTS ERRED IN THEIR CONSTRUCTION OF THE PHRASE "ACCOMPANYING SUCH ARTICLE" BY EMPLOYING THE TEST OF "TEXTUAL RELATIONSHIP" RATHER THAN "PHYSICAL CONTIGUITY"

The entire tenor and philosophy of food and drug regulation under Federal statute centers about the *product* and its transportation in interstate commerce. Thus, misbranding is not unlawful in itself; it is the interstate shipment of an article that is at that time misbranded that constitutes the offense. *Weeks* v. *United States*, 245 U. S. 618, 622. This was not only due to Congressional doubts prevailing at the turn of the century as to the constitutional validity of "interstate commerce" legislation dealing with the solicitation of sales and the expressions of opinions,[6] but also rests on practical considerations. Thus, Fisher has pointed out in discussing S. 1944 (73rd Cong., 1st Sess., 1933)—one of the bills preceding the Federal Food, Drug, and Cosmetic Act:

> "The bill's novelty lies in the manner of its attempt to control advertising: it scores not the

[6] *Cf. United States* v. *Johnson*, 221 U. S. 488, 498, in which Justice Holmes avoided discussion of "the limits of constitutional power" but went on to imply that the Congress might, in governing therapeutic claims, "distort the uses of its constitutional power." The subject was only clarified in 1916 by the decision of *Seven Cases* v. *United States*, 239 U. S. 510, 514, 515. See also *Crenshaw* v. *Arkansas*, 227 U. S. 389, 396.

> movement of falsely advertised food, drug, or cosmetic packages in interstate commerce * * *. This failure to forbid the actual inundation of interstate commerce * * * narrows the scope of the control and the failure to apply the seizure provisions of the law to such articles may rob the bill's false advertising anathema of most important sanctions. *Their application would, of course, present the difficult problem of determining how long and over what territory a false advertisement would justify seizure.*" (Italics added.)[7]

Since the emphasis of the statute is on the product—whether it be food, drug, device, or cosmetic—it follows that printed matter, such as circulars, advertisements, pamphlets and books, possessed of a distinct identity and character *apart* from a particular food or drug, thereby loses its basic essence as "labeling" and, moreover, fails to come within the jurisdiction of the Federal Food, Drug, and Cosmetic Act whose terms are confined to the article and only printed matter incidental to, dependent upon, and physically connected with, it. *United States* v. *7 Jugs, etc., Dr. Salsbury's Rakos,* 53 F. Supp. 746. The concept of "textual relationship," conjured up by the circuit court of appeals (R. 464), breaches this fundamental principle since it is based on *mental,* rather than physical, association without reference to a particular shipment. Notwithstanding the conclusions of some lower courts, the theory of the regulation as a whole, the source of the statutory

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[7] Fisher, "The Proposed Food and Drugs Act: A Legal Critique," *Law and Contemporary Problems,* Vol. 1, No. 1 (December, 1933, p. 77). The final bill, as amended, omitted the advertising provisions. Congressional intent is evident from the debate in the House on the first S. 5 (80 Cong. Rec. 10230-10244, 1936) and on the final measure (83 Cong. Rec. 391-424, 1938) and in the Senate on the conference report (83 Cong. Rec. 3287-3293, 1938).

terminology, the phraseology of the definition, and the legislative history, all make it clear that "labeling," as defined in section 301(m) [21 U. S. C. 321 (m)], is limited to printed matter physically accompanying a particular food or drug during its movement in the channels of interstate commerce. This is obviously true of adulteration (where the deterioration or defect must be associated with a specific product) and only loose thinking changes the rule in the case of misbranding.[8]

The term "labeling" is patently a word of legislative art, defined by section 201 [21 U. S. C. 321] as:

> SEC. 201. For the purposes of this Act—
>
> • • • • • •
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.[9]

What is not as evident but of equal importance is that the phrase contained in the definition, "accompanying such article," is also a "word-of-art," so to speak, it being the declared intention of the drafters of the statute and of the

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[8] "Adulteration" and "misbranding" are frequently sides of the same coin. It has been observed: "Actually a relatively large proportion of 'misbranding' and 'adulteration' represents only different designations applied to the same wrong; • • •." Herrick, *Food Regulation and Compliance*, Vol. II, p. 649.

[9] Regulation §2.2, to this section of the statute, adds the further interpretation that "labeling" includes "all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce." However, this regulation does not add to or expand the statutory definition (*United States* v. *Antikamnia Chemical Co.*, 231 U. S. 654) and, moreover, is not controlling on the court (*United States* v. *W. B. Wood Manufacturing Co.*, White and Gates *Decisions of Courts—Federal Food and Drugs Act*, pp. 1002, 1003, affirmed 292 Fed. 133 (C. C. A. 8, 1923)).

Congress to extend to it the significance developed by the courts in earlier decisions under the Federal Food and Drugs Act of 1906.[10] As a matter of fact, the expression was taken almost verbatim from a decision of this Court, presumably with the object of having it carry the meaning therein expounded.

Thus, when the original Food and Drugs Act, enacted in 1906 (34 Stat. 768) was ruled to be inapplicable to false or misleading therapeutic claims made on the package or label of a drug (*United States* v. *Johnson*, 221 U. S. 488), the judicial limitation of its application was met by the enactment of the so-called "Sherley amendment" [Act of August 23, 1912, ch. 352, 37 Stat. 416], which extended the law to drugs whose

> "* * * package or label shall bear or contain any statement * * * regarding the curative or therapeutic effect of such articles or any of the ingredients or substances contained therein, which is false and fraudulent."

The constitutionality of the Shirley amendment was considered by this Court in *Seven Cases* v. *United States*, 239

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[10] The adoption of terms and phrases already judicially construed was carried out throughout the Federal Food, Drug, and Cosmetic Act. The advantages of such a course are obvious, although there is no reason why it should be available to the prosecution when it suits its purpose, to be ignored where it may see an opportunity to enlarge its powers. To illustrate the adoption, the term "package," used in the earlier statute was changed to "immediate containers" in the present law (section 231 (k)) to take advantage of the statutory interpretation expressed in *McDermott* v. *Wisconsin*, 228 U. S. 125. This dependence on court decisions is admitted in Senate Report No. 361, to accompany S. 5, 74th Cong. 1st Sess., p. 2: "In drafting S. 5 the language of every worthy provision of the present law has been included. Only that language which afforded loopholes for the escape of the unscrupulous has been rejected. *Court decisions on the provisions that have been perpetuated will thus continue to be applicable.*" (Italics added.)

U. S. 510 and it is in this Court's opinion that we find, for the first time, the expression "accompanies the article."

The case involved statements set forth in a circular *packed with each bottle of the medicine.* It was argued that the amendment of 1912 did not embrace circulars contained *in* the package, but applied only to those statements appearing *on* the package or *on* the bottles. This Court, however, refused to be limited by this restrictive interpretation, and, in over-ruling it, used the language (p. 515):

> "* * * And the power of Congress manifestly does not depend upon the mere location of the statement *accompanying the article,* that is, upon the question whether the statement is *on* or *in* the package that is transported in interstate commerce." (Italics supplied in part.)

At a later point in the decision it repeated (p. 517):

> "The false and fraudulent statement, which the amendment describes, *accompanies the article in the package,* and thus gives to the article its character in interstate commerce."[11] (Italics supplied.)

In adopting this phrase, there is little doubt that the drafters of the present law, and the Congress in enacting it, sought to perpetuate the import of the *Eckman* decision—namely, that "labeling" included printed matter *accompanying the article in the package.* Indeed the very termi-

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[11] The same language, with the identical limitation as to *physical* association, was later used in a charge made to a jury in *United States* v. *11 Packages of B. & M. External Remedy,* White and Gates *Decisions of Courts—Federal Food and Drugs Act,* pp. 1059, 1063. The court was evidently following a request made by the United States attorney, a customary procedure. It charged: "If they were false, it makes no difference whether the statements were printed on the label on the bottles, on the cartons or containers in which the bottles were shipped, or in circulars, pamphlets, or booklets *accompanying the shipment.*" (Italics supplied.)

nology of the statutory definition discloses this intention. Thus, it lists printed matter (*d*) upon the article itself, (*b*) upon its container or wrapper, and (*c*) accompanying such article, *i. e., in the package.* Were it the purpose to establish a *new* category embracing material physically apart from the article it is reasonable to assume that the Congress would have used language expressly so stating or substantially as follows: "(1) upon any article or on or *in* its container *and* (2) accompany the article."

The subparagraph "(2)" as it now stands in section 231(m) patently relates to enclosures *in the consignment involved* only. This is also made evident by the Senate report on an earlier version of a bill bearing the same terminology (Senate Report No. 361, to accompany S. 5, 74th Cong., 1st Sess., p. 4):

> "This differentiation between *label* and *labeling* is necessary because the declaration of certain facts for the information and guidance of consumers required on the label by the substantive provisions of the bill should, to accomplish their purpose, appear on the principal label or labels where they can be easily observed, rather than on side panels of the labeling or *in circulars within the package* where they may escape notice."[12] (Italics supplied.)

Also indicative of the Congressional intent is the fact that, as we have observed, the earlier drafts of the Act were

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[12] Nor is this significance changed, as appellee will probably contend, by the testimony of Walter G. Campbell at the hearings before a subcommittee of the Committee on Commerce (U. S. Senate, 2d Sess., p. 16) in which he makes reference to "labeling" including "circulars and material and placards for display purposes and the like that may in any form whatever accompany the article * * * ." Mr. Campbell was obviously referring to the practice of including this type of material *with* the shipment. He said nothing of physical separation or shipment and the impression he conveyed to the subcommittee is clearly reflected in the Senate report quoted above.

drafted to include regulation over the *advertising* as well as the labeling of a food, drug, or cosmetic. Thus, S. 2800[13] contained the following definitions distinguishing the two concepts:

> "SEC. 2. As used in this Act, unless the context otherwise indicates—
>
> * * * * * * *
>
> (i) The term 'labeling' includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any food, drug, or cosmetic.
>
> (j) The term 'advertisement' includes all representations of fact or opinion disseminated in any manner or by any means other than by the labeling."

Yet when control over advertisements of these products was transferred to the Federal Trade Commission,[14] the definition of "labeling" was allowed to remain substantially as it had—it was not expanded to include material of mental or "textual" nature such as is involved in this case! Evident here is the intent to exclude advertising material from the embrace of "labeling."

Nor was the concept that "labeling" included printed matter wholly separated physically from the shipment invoked—or even recognized—during the first years in which the present Act was in force. On the contrary, this theory seems to have been presented to the courts only within the past few years, held in reserve, so to speak, until a body of preliminary law could be built up to buttress still a

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[13] Reprinted in full in Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess., pp. 1-12.

[14] See note 7, *supra*.

further advance into the field of independent advertising material.[15]

Appellant's interpretation is supported, not only by historic precedent, but by every rule of construction and logic. The sole approach to enforcement was, and is, directed at the *article*, be it food, drug, device, or cosmetic. For example, the law reads:

> "SEC. 502. A *drug* or *device* shall be deemed to be misbranded—(a) if *its* labeling is false or misleading in any particular." (Italics supplied.)

Nor does the statute authorize proceedings against printed matter *per se*. "Labeling" does not, indeed cannot, possess a separate identity or existence of its own *apart from a specific food, drug, or cosmetic;* its is but a satellite's position, revolving intimately about a particular food or drug. Lacking this physical bond, this physical attachment, this physical dependence, the printed material loses its character *as labeling* and hence is not subject to the provisions of the Act. That this elementary principle was ignored by the prosecution and the lower courts is evident.

There is no doubt that in the case at bar this essential relationship of article to circulars was overlooked, or paid lip-service only at best. Obviously, the Government first directed its attention to the booklets, pamphlets and circulars. The article, it seems clear, did not enter into this preliminary investigation. Indeed, it was only *after* it concluded that the printed material bore actionable repre-

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[15] Cf. the step-by-step evolution presented by *United States* v. *Research Laboratories, Inc.*, 126 F. 2d. 42, *cert. den.* 317 U. S. 656; *United States* v. *Lee*, 131 F. 2d 464; and *United States* v. *7 Jugs, etc. Dr. Salsbury's Rakos*, 53 F. Supp. 746. The encroachment was stopped by *United States* v. *Alberty*, 159 F. 2d 278, and again by *United States* v. *Urbeteit*, 164 F. 2d 245, but not before the circuit court of appeals below had given its stamp of approval to the broadening assumption of power.

sentations that it cast about to line up, if it could, an interstate shipment of a food or drug—whose only connection with the printed material was that it bore the same title as that appearing in the booklets or circulars—to give its prosecution some semblance of compliance with the jurisdictional requirements of the law.[16]

Here is no legitimate prosecution of a breach of the Federal Food, Drug, and Cosmetic Act, as enacted by the Congress. On the contrary, in this instance we can only recognize an effort by a governmental agency to distort the purposes of its creation, to extend its power, by indirection and usurpation, to a field which the Congress deliberately and expressly excluded from its authority. See note 7, *supra*.

That this indignation of expression is warranted becomes evident when we examine the disparities of the interstate journeys of the articles alleged to be misbranded and their alleged "labeling." For the convenience of this Court, a chart is submitted, showing the dates of introduction into interstate commerce of the alleged misbranded articles involved and the subsequent or prior period, as the case might be, that elapsed or ensued before the so-called labeling was shipped. [See Fig. 1, p. 4, *supra*.] In none of these instances does it appear that the printed material accompanied the article when it was introduced into interstate commerce. On the contrary, at the time the article was shipped, the printed material was either not in existence or was so far removed from the article physically as to negate any suggestion that it "accompanied" it.

Appellee's attempted nexus between the article and the printed matter will, no doubt, be the assertion that the cir-

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[16] One need only examine the haphazard collection of shipping dates of article and "labeling"—running as far apart as almost *two years*—to realize how hard put the Government was to find a shipment upon which to prosecute.

culars were essential to the proper use and purpose of the product. The argument may be recognized as but a desperate attempt to save its theory of accompaniment. Even the circuit court of appeals acknowledged (R. 462) that:

> "The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage, and in some cases, the alleged daily minumum requirement of the vitamins and minerals therein * * *."

But what other data are necessary to the proper utilization of such common articles so familiar today to almost every person in the land? Each product was labeled with the information required by law. Thus, the BOLAX label read (R. 35-6):

50 Tablets—Price 50¢
Lelord Kordel's
BOLAX
Laxative
Tablets

Contains Powdered T. V. Senna Leaves, Uva Ursi Leaves, Buckthorn Bark, Licorice Root, Red Clover Tops, Coriander Seed, Elder Flowers, Pale Rose Buds, Peppermint Leaves, African Ginger Root, Fennel Seed, Mexican Saffron, Aniseed, Cyani Flowers.

Distributed by
LELORD KORDEL PRODUCTS
RUSS BLDG. * SAN FRANCISCO

DIRECTIONS: One to two tablets. Children: One-half to one tablet or less, in proportion to age. To avoid any possibility of forming the laxative habit, this preparation should be taken only when necessary. It should never be taken in cases of nausea, vomiting, abdominal pains and other symptoms of appendicitis.

In this case, moreover, the product was shipped to the dealer on July 10, 1942. Is this Court expected to believe that the article was held—either on the dealer's shelf or in the purchaser's medicine chest—until January 18, 1944 (over 18 months!), awaiting the receipt of information regarding its "intended uses"?

Furthermore, there is not one iota of evidence that the ultimate consumer relied on or required the circulars either in purchasing or using the products. Vitamins, minerals, and herbs such as these do not ordinarly call for special directions for their use; the label gives adequate information. Nor is it an unreasonable assumption that they were used without especial instructions. If the Government's theory were otherwise, certainly it should have produced witnesses to so testify; it did not.

Nor, it must be apparent to any one reading the record, was the case brought or tried on the principle that the consumer bought or used the product in reliance on the advertising material. The only association of printed matter and goods is that at one time or the other they passed through the hands of a particular dealer.

Adoption of the circuit court of appeal's theory can, moreover, lead only to a complete distortion of the law. In defining "accompaniment" in terms of "textual relationship" rather than "physical contiguity," Judge Sparks has departed further from established legal principles than has ever been attempted before. He has taken a statute that by its title is concerned with the prohibition of "the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics * * *"—all *physical* objects—and made of it a law dealing with intangibles occupying neither time nor space.

In its most elementary sense this decision implies that the mere statement in a publication years before or years

after the physical introduction of the article into interstate commerce may irrevocably misbrand that product if it can be shown that the representation was objectionable. It is but a short step further to state that an advertisement appearing in a San Francisco paper in 1947 "misbrands" a drug shipped to New York in 1945. And even where the destinations are the same, the utter illogic of this contention is evident when one realizes that the product has, in all probability, been wholly consumed long before the false or misleading statement is even uttered. This is indeed an intolerable rule for drugs where opinions are always in flux and no certainty exists. *Cf. American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94; *Raladam Co.* v. *Federal Trade Commission*, 42 F. 2d 430, *affirmed other grounds*, 283 U. S. 643; *United States* v. *Johnson*, 221 U. S. 488; *Seven Cases* v. *United States*, 239 U. S. 510.

To avoid the opening of such a Pandora box of confusion and uncertainty, this Court should affirm the logic of the *Urbeteit* decision (164 F. 2d 245, 246) where it was stated:

> "The claim alleges the printed matter was mailed Sept. 1. It did not 'accompany' in any fair sense either shipment. Both the amended libel and the second amended libel allege that the false leaflets 'accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce.' This is the exact language of section 304(a), the forfeiture provision of the statute, but it is shown not to be true of any shipment. The first three shipments went forward and were received by Kelsch, and put to work in his medical practice several weeks before any leaflets were sent. They did not accompany any of the devices while they were in interstate commerce. The last shipment went forward three weeks behind the leaflets, and was not accompanied by them.

Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched." (Emphasis added.)

II.

THE EVIDENCE WAS NOT DIRECTED AT OR DID IT ESTABLISH THAT APPELLANT VIOLATED SECTION 301 (a).

Where the violation charged is that the food or drug was, at the time of its introduction into interstate commerce, "then and there" misbranded, printed matter shipped days, months, and years from that time cannot be considered in judging whether the product was so misbranded. Section 301, subsections (a), (b), (c) and (k), makes a different offense of each step in the interstate journey of a product, all necessarily distinct and exclusive of each other (*United States* v. *Sullivan*, 332 U. S. 689), and misbranding *subsequent* to introduction into interstate commerce must be prosecuted as an offense of a different nature. This was not done in the case at bar, the evidence introduced being directed at offenses not charged. By analogy, a food that becomes adulterated after its introduction into interstate commerce cannot support a criminal charge against the shipper, since, judged at the time of shipment, his hands are clean. The same rule is patently applicable to misbranding.

In each of the informations referred to it is notable that the date of the introduction of the food or drug into interstate commerce differs from the date of the introduction of the circular, pamphlet, or booklet, the difference extending from two days to almost two years (see Fig. 1, p. 4, *supra*). In several cases, moreover, the printed material was shipped from Mendoza, Illinois—not Chicago, Illinois, the place of origin of the article. *None of these ship-*

ments of the article, if sampled at the moment of its introduction into interstate commerce, would have been found to have been accompanied by the alleged violative "labeling."

The Federal Food, Drug, and Cosmetic Act [21 U. S. C. 331] sets forth a series of "PROHIBITED ACTS," which constitute offenses under the statute. Material to this appeal are the following:

> "SEC. 303 (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> "(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
>
> "(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
>
> • • •
>
> "(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or *the doing of any other act with respect to* a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." (Italics supplied.)[17]

The carefully drawn pattern of the enforcement scheme of the statute becomes apparent in examining these provisions. The Congress saw that an offense might occur (1) at the point of the article entering interstate commerce; (2) while it was in interstate commerce; (3) on resale after its receipt in interstate commerce; and, to cover all contin-

[17] This section has been amended since this case was brought.

gencies, (4) if it were misbranded while being held for sale after its interstate shipment. The time sequence of the series is obvious; the Congress made an offense of misbranding at each step in the trip between the shipper and the consumer, but, in doing so, made each offense separate and distinctive of the others. Thus, one offense does not begin until the prior enumerated offense terminates; nor can an offense relating to one segment of the interstate journey and distribution overlap or project itself back to another period in the trip. In short, each offense is exclusive of the others and designedly so.

It is material to note that the charge in *United States* v. *Sullivan*, 332 U. S. 689, was violation of section 301(k), and this Court was careful to call attention to the pattern of regulation extending coverage of the law "from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer," emphasizing the separate nature of each step.

Appellant has been charged in this case *only* with the first offense enumerated, that is, the introduction or delivery for introduction into interstate commerce of a drug that is misbranded. That, and that alone, is the gravamen of the charge. But where the violation occurs *after* the article has been introduced into interstate commerce there can be no breach of this provision. It is recognized, of course, that a subsequent misbranding may create *another* offense, but this fact "has no application to a charge that at the moment of introducing the drug into interstate commerce the misbranding 'then and there' occurred." *Alberty* v. *United States*, 159 F. 2d 278, n. 1.

That no violation of the prohibition against the introduction of a misbranded or adulterated article into interstate commerce takes place *unless* the article is misbranded

or adulterated *at the time of its introduction* has long been the rule and is supported by many authorities. See, for example, *Weeks* v. *United States*, 245 U. S. 618; *United States* v. *94 Doz. etc. Capon Springs Water*, 48 F. 2d 378; *United States* v. *J. L. Hopkins & Co.*, 199 Fed. 649; *United States* v. *5 Boxes of Asafoetida*, 181 Fed. 561. As a matter of fact, the circuit court of appeals for the ninth circuit has handed down a decision exactly in point (*Alberty* v. *United States*, 159 F. 2d 278). So completely controlling to the case at bar is the lucid and compelling exposition of Judge Denman in that decision that appellant is impelled to quote from the opinion at some length (p. 279):

"Section 331 (a) provides

'Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that *is* adulterated or misbranded.' (Emphasis supplied.)

It will be noted that the verb 'is' is in the present tense. Section 331 (a) confines the offense to a misbranding at the 'introduction or delivery for introduction into interstate commerce' as recognized in the information by the use of the words 'then and there.'

"A drug is misbranded 'If its labeling is false or misleading in any particular.' 21 U. S. C. §352(a) 'Labeling' of an article is defined to mean 'all labels * * * accompanying such article.' 21 U. S. C. 321 (m).

"The information charges that the false labels were shipped by appellant to the Natural Food Store at Kansas City, Missouri, on February 7, 1944, that is two months and eleven days before April 18, 1944, when the drug was 'then and there' introduced into

interstate commerce. It does not allege that the labels were to be placed with the drug or used together with it by the consignee. For all the information alleges, the labels may not have arrived in Missouri. Or they may have been destroyed. Or they may have been distributed to the prospective customers a month before the arrival of the drug in Missouri and hence never accompanied it there. Or they may have been used in connection with other drugs shipped and sold long prior to April 18, 1944, when the charged offense is alleged 'then and there' to have been committed.

"We do not think that the bald statement that the labels were shipped to the Missouri consignee seventy-one days before the drug was shipped charges the offense of causing them to be 'accompanying' the drug's introduction into interstate commerce on or about April 18, 1944."

The court concluded (p. 280):

"* * * the case was tried on a stipulation of facts which stated that the shipment of labels was received by the consignee on February 11, 1944, and the drug on April 25, 1944, clearly establishing that the two did not accompany each other when introduced into interstate commerce or at any time in that interstate transit. It was also stipulated that they were exhibited together in the consignee's store. Here there might be said to be accompaniment *after* the interstate commerce was completed, but nothing is stipulated as to appellant's then ownership or control of the drug and labels or her participancy in these later acts to bring her within 331(k), a section not involved in the information."

The persuasion and logic of this argument makes it almost unnecessary to emphasize other jurisdictional aspects evidently overlooked by the lower courts in finding

appellant guilty on these counts. The circuit court of appeals for the fifth circuit found it controlling in the *Urbeteit* case (164 F. 2d 245, 246). Indeed, Judge Sparks in the instant case went counter to it only "to the extent that the court limits the definition of the word 'accompany' to mean only physical association and continguity" (R. 467), implying verbally—if not by his final conclusion—that he agreed with the separation of offenses that in the final analysis served as the basis of the *Alberty* decision. This Court, in *United States* v. *Sullivan*, 332 U. S. 689, also acknowledged its logic by implication.

A further rule of construction of the statute justifies a reversal on this ground. As this Court emphasized in *Weeks* v. *United States*, 245 U. S. 618, 622:

> "The statute does not attempt to make either kind of misbranding unlawful in itself, but does, as before indicated, make it unlawful to ship or deliver for shipment from one State to another an article which is misbranded in either way."

Thus it is not the mislabeling that supplies the basis of the offense, but rather the *act* of introducing, or delivery for introduction of, the already *misbranded* article into interstate commerce. (*Cf. United States* v. *Dotterweich*, 320 U. S. 277.) That the article is subsequently rendered mislabeled has no relation to the act of introduction of a *misbranded food or drug* if it were not, in actual point of fact, misbranded *at that time.*

III.

GOVERNMENT'S EXHIBITS 8 AND 24 DID NOT "ACCOMPANY" ANY ARTICLES AT ANY TIME IN INTERSTATE COMMERCE, OR THEREAFTER, BUT WERE INTENDED FOR, AND ACTUALLY USED AS, "MAILING PIECES"

An examination of Government's Exhibits 8 and 24[18] shows that they bear a post-office mailing permit indica, together with space for addressing. They are obviously "mailing pieces," intended to be addressed and introduced into the United States mails by the dealer as advertisements. They were, moreover, shipped separately from the articles with which they are now associated as "labeling."[19] The evidence is clear that the sole purpose of their shipment by the appellant to the dealers was for mailing (R. 145, 146, 161, 167, 335). It is interesting to observe that the United States attorney himself pointed out that, *unless* the postal insignia were blocked out, it constituted a violation of law to distribute them other than by mailing (R. 148). Government witnesses also established that most, if not all, of the circulars and magazines were actually mailed (R. 146, 161, 167), or were addressed for mailing when seized by the United States Marshal (R. 147). In both instances, furthermore, the printed material was generally held, for addressing and mailing, separate from the retail portions of the stores (R. 150, 162, 166).

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[18] The so-called "Gotu Kola" circular and the magazine entitled "Health Today Spring 1945."

[19] Government Exhibit 24 was shipped in interstate commerce *six months* before the consignment of the article; Government Exhibit 8 was shipped *36 days* after the articles with which it is now connected. Both were shipped directly from the printers, one in Mendota, Ill. (R. 4), the other from Chicago (R. 50, for instance); neither, however, from the same premises or address from which the merchandise was shipped.

In no case of record that counsel can find has it ever been held, or, indeed, suggested, that a circular or magazine—intended solely for mailing through the United States mails, and, in fact, violating the law if its distribution were otherwise diverted—constitutes "labeling" by reason or the mere accident of its presence on the same premises as the food or drug. Even the decisions relied upon by the trial court failed to go to these lengths of misunderstanding. For example, in *United States* v. *Research Laboratories, Inc.*, 126 F. 2d 42, *cert. denied* 317 U. S. 656, the article and the circular involved not only had a *common* destination—wholly lacking in the case at bar where the *eventual* destination was as wide-flung as the mailing list—but, in addition, arrived at their destination simultaneously. In *United States* v. *Lee*, 131 F. 2d 461, the circular physically accompanied the product *over-the-counter* at the time of sale, both being offered to the purchaser at the one time. And in *United States* v. *7 Jugs, etc., Dr. Salsbury's Rakos*, 53 F. Supp. 746, 755, the court emphasized that:

> "What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, *display, distribution and use together.*" (Italics supplied.)

None of these "vital factors" is present in the case at bar. Certainly, there is no "common origin, common destination, display, distribution and use together" where circulars and magazines are intended for, and actually used, as mailing pieces, and whose only connection with the articles is that they are being addressed and mailed from the rear of retail premises in which the articles may be stocked.

The Government, evidently realizes the weakness of its case, made an effort to prove that several copies of Health

Today Spring 1945 had had the mailing insignia stamped out (Government's Exhibit 10, R. 148, 384-6) *by the dealer* for purposes of distributing them over-the-counter (R 335). The precise testimony is interesting:

> "The Witness: Yes, that bears our stamp. We affixed that rubber stamp over this printed mailing franchise here for the purpose of handing them out over the counter. (R. 148) Q. Who placed that on there, do you know? A. Some of our employees. Q. Under your direction? A. Yes. (R. 334) Q. You put that rubber stamp on after you received it, didn't you? A. Yes. (R. 335)[20]

How the lower courts could attribute such an act to the appellant, under the informations charged against him, is impossible to understand. However, that it served some basis for the judgment is evident from the finding of guilty on all counts, including those supported by these Exhibits. There is no doubt, of course, that the dealer was not an agent of appellant, (*United States* v. *Boise Valley Co-operative Creamery Co.*, White and Gates, *Decisions of Courts—Federal Food and Drugs Act*, p 1203). Nor was any evidence introduced that the appellant had directed or authorized this alteration (R. 149). If such an act occurred, and constituted misbranding as charged, prosecution could, and should, as a matter of fact, have been brought *against the dealer* under 21 U. S. C. 331(k)—certainly, however, not the appellant (*Alberty* v. *United States*, 159 F. 2d 278; *United States* v. *Lee*, 131 F. 2d 464).

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[20] This testimony concerned only Government's Exhibits 8 and 10. As to Government's Exhibit 24, a prosecution witness testified: "On a circular like that we never leave them in the store for customers to pick up . . ." (R. 162-3).

IV.

A BOOK, PRICED FOR SALE AND ACTUALLY SOLD, DOES NOT "ACCOMPANY" AN ARTICLE IN INTERSTATE COMMERCE, AND DOES NOT CONSTITUTE "LABELING"

Government's Exhibits 8A, 8B, and 8C are three so-called "health books," entitled *Nutrition Guide, Arthritis* and *The Art of Relaxation*. The *Arthritis* and the *Nutrition* titles were plainly marked with their price; the *Relaxation* title, by one Charles B. McFerrin, was published and distributed by appellant. All were sold by dealers; none was distributed to customers in the stores as advertising matter (R. 132, 146).[21] Indeed, even the Government inspector was required to pay for the books he took as evidence (R. 140). The prosecution claimed, and the lower courts have found, that these books, in effect, "accompanied" drugs in interstate commerce and constituted "labeling" (R. 443).

To place such a construction on these books patently distorts the intendment of the statute to its utmost. Holding a book, priced for sale and distributed only on payment of its purchase price, to "accompany" an article referred to by name in its pages, is so utterly laborious and strained an interpretation as to defy justification on any grounds. By the same token, every article on the shelves of a store "accompanies" every other article, despite the fact that each calls for a separate and distinct sales transaction. In subscribing to such a concept, what happens to the factors of "interdependence of the drug and the booklets • • • display, distribution and use together" relied on in *United*

[21] One Government witness, for example, testified that the *Arthritis* manual was only sold; was never given away; and could be purchased separately from the articles (R. 133).

States v. *7 Jugs, etc., Dr. Salsbury's Rakos,* 53 F. Supp. 746, 755? Where, too, is the element of physical accompaniment at the time of the sale of the article forming the basis of the decision in *United States* v. *Lee,* 131 F. 2d 461? Yet these cases were cited by the prosecution and the lower courts and served as the basis, evidently, of the judgments below.

While it may be true that Regulation §2.101, under Section 502(a) of the statute, provides that false or misleading representations in the labeling of one *drug* with respect to another *drug* may render the first misbranded, it does not follow, that false or misleading representations in a book about a drug renders the book misbranding—or, for that matter, the drug so mentioned. The statute asserts no jurisdiction over books *per se.* Indeed, once a book acquires a distinct identity of its own *as a commodity*—and surely it does so when it becomes the subject of an individual transaction, as in this instance—it is not amenable to the Federal Food, Drug, and Cosmetic Act for the obvious reason that it is not a food, drug, device, or cosmetic.

This example illustrates the fallacy of the prosecution in construing "labeling" as it has done. As has been argued, printed material possessed of existence and being *physically apart* from the article cannot, in logic, be proceeded against, since it is outside the jurisdiction of the statute. To attempt, as the Government has done throughout this case, to provide the essential nexus merely by a mental association of words—briefly, by "reference"—rather than a physical connection, makes a mockery of the Congressional intent in enacting this legislation. This is no better exemplified than in the effort to characterize a book, actually and independently sold, as "labeling" to another article, also separately sold.

V.

THE PRINTED MATTER INVOLVED IS ADVERTISING MATERIAL AND NOT LABELING SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Although, in a broad sense, labeling may be considered a form of advertising,[22] nevertheless the two terms are, of course, not synonymous and a distinction has been recognized and drawn in various legislation.[23] Moreover, the fact that *labeling* may in some respects have the same purpose as advertisements does not conversely authorize the courts to characterize forthwith all *advertising* as "labeling." The circuit court of appeals overlooked the basic logic of this proposition when it ruled what was obviously advertising material to be labeling (R. 463). *Urbeteit v. United States*, 164 F. 2d 245.

In holding as they did, it is clear that both lower courts stretched the import of the Federal Food, Drug, and Cosmetic Act to snare the appellent under any pretense for his alleged "heinous crimes." They were obviously trying a "self-styled authority on nutrition and vitamins" (R. 462), rather than a specified violation of a particular Federal statute.

Thus both tacitly admitted that when the products were introduced into interstate commerce they were properly

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[22] This Court, for instance, in *Rast* v. *Van Deman & Lewis Co.*, 240 U. S. 342, said: "Advertising is merely identification and description, apprising of quality and place. It has no other object than to draw attention to the articles to be sold * * *"

[23] Thus, the Federal Trade Commission Act, section 15 (a) [15 U. S. C. 55(a)] defines "false advertising," expressly excluding labeling from the purview of the expression; and the Federal Alcohol Administration Act [27 U. S. C. 205(f)] generally defines "advertising," developing the definition in greater detail in the issued regulations. §61, Regulation 4.

labeled. But this very honesty was viewed as a devious "scheme" (R. 465)! However, despite the efforts of the courts to "protect" the public from "quite harmless" drugs (R. 465), to construe separate advertising material, whose only connection with the article is the similar name of the product, as "labeling," on the ground that it would "permit evasion of the Act" ignores Congressional intent and totally overlooks, morever, that at least two *other* Federal statutes could deal with this printed matter were it unlawful. As a matter of fact, the Federal Trade Commission Act and the Criminal Code (§215, 18 U. S. C. §338) both have jurisdiction over such acts. Certainly it is not necessary to distort the scope and intendment of the Federal Food, Drug, and Cosmetic Act to bring a culprit to justice. Again, if the possibility of evasion exists, it is the duty of the Congress to correct the situation, not the courts.

VI.

APPELLANT WAS ENTITLED TO A STRICT CONSTRUCTION OF THE ACT WITH PROOF OF VIOLATION, IF ANY, BEYOND A REASONABLE DOUBT

In implying that appellant was not entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt,[24] the lower courts abused one of the most elementary rules of criminal law, if not expressly, then in their mental concept of the weight of evidence. There can be no argument that in a criminal

[24] The circuit court of appeals paid lip-service to part of the rule by concluding its discussion of the argument with the statement "We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt" (R. 466). The trial court clearly gave the impression that this degree of proof was unnecessary in this case (R. 441, 443).

prosecution the Government throughout the trial has the *onus probandi*—the burden of proving beyond a reasonable doubt all the essential elements of the offense charged and the guilt of the accused. *United States* v. *Resnick*, 299 U. S. 207; *Holt* v. *United States*, 218 U. S. 245; *Agnes* v. *United States*, 165 U. S. 36. The rule is no different in criminal cases arising under the Federal Food, Drug, and Cosmetic Act. Indeed, in a recent decision of the third circuit, the court reversed a conviction for the mere failure of the trial judge to so charge without ambiguity. *United States* v. *Crescent-Kelvan Co.*, 3 Cir. (decided January 26, 1948).

Yet we find the trial court finding that the Federal Food, Drug, and Cosmetic Act, "being 'remedial legislation,' the rule of liberal construction is to be followed irrespective of its penal provisions" (R. 441) and, in effect, treating this prosecution as a civil proceeding. In fact, it went further. In justifying its "liberal construction" it remarked (R. 443) that "the element of forfeiture in a statute is as much a penal provision as is the one imposing a penalty," without appreciating that the general rule in this connection is that "statutes imposing forfeitures, being penal in nature, are to be strictly construed in favor of the defendant." *C. C. Co.* v. *United States*, 147 F. 2d 820, 824. The circuit court of appeals compounded this error (R. 466).[25]

Evidently overlooked by the courts was the fact that the statute is, in a very real sense, an "omnibus" law, providing for civil, criminal, and administrative enforcement.

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[25] The court cited, in support, *United States* v. *Dotterweich*, 321 U. S. 277, which, of course, merely makes it unnecessary in these prosecutions to prove criminal knowledge and intent. In fact, this Court reiterated its confidence in established legal experience and principles—"the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries."

The Government would be the first to acknowledge that the degree of proof required in its administrative proceedings differs from that of civil or criminal cases (*Cf. The James J. Hill,* 65 F. Supp. 265). Moreover, the *objective* of its enactment has no bearing on the *construction* of the various remedies available to the Government. Penal statutes whether incorporated in general statutes or not, are clearly subject to a strict construction and are to be interpreted strictly against the Government and liberally in favor of an accused (*United States* v. *Resnick,* 299 U. S. 207).

In *Alberty* v. *United States,* 159 F. 2d 278, 280, the ninth circuit distinguished between the construction in civil proceedings and in criminal prosecutions arising from this very statute. In dismissing the cases cited by the Government in its brief, it remarked:

> "These three cases were civil proceedings and not criminal prosecutions. They construe the Act liberally."

The court went on to quote *Kraus & Bros., Inc.* v. *United States,* 327 U. S. 614, 621, which, it pointed out, construed "in a criminal proceeding the Emergency Price Control Act which, like the Food, Drug, and Cosmetic Act, also afforded civil relief." The language of this Court so repeated was:

> "This delegation to the Price Administrator of the power to provide in detail against circumvention and evasions, creates a grave responsibility. In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. *Hence to these provisions must be applied the same strict rule of con-*

struction that is applied to statutes defining criminal action. * * *" (Italics supplied.)

As this Court stated in *United States* v. *Sullivan*, 332 U. S. 689, 693-4, criminal statutes "should be given their fair meaning in accord with the evident intent of Congress. *United States* v. *Raynor*, 302 U. S. 540, 552." But this does not mean that so-called "remedial legislation" should be treated as a "blank check" from the Congress to enforcement agencies, permitting all forms of distortion and a callous disregard of constitutional rights in the name of "liberal construction." We have been taught that Liberty is not License—the aphorism is likewise applicable to our subject.

There appears no doubt that, in their anxiety to accomplish the "remedial" objects of the law, the lower courts overlooked the essential requirement that, even in this type of legislation, the burden, in proceedings for violating the criminal provisions of the statute, is upon the Government to establish its case beyond a reasonable doubt (*Von Bremen* v. *United States*, 192 Fed. 904 (C. C. A. 2, 1912); *United States* v. *Newton Tea & Spice Co.*, 275 Fed. 394; *United States* v. *American Laboratories*, 222 Fed. 104; *United States* v. *Mayfield*, 177 Fed. 765). A reading of the record makes it clear that the prosecution failed to prove its case against appellant beyond a reasonable doubt. The mental attitude of the trial court, moreover, was such that it did not look for this high degree of proof. The failure of the trial court to keep in mind this elementary safeguard of the appellant's constitutional rights is clearly reversible error.

VII.

IN VIOLATION OF HIS CONSTITUTIONAL RIGHTS, APPELLANT WAS PROSECUTED BY INFORMATION INSTEAD OF BY INDICTMENT.

The Fifth Amendment to the United States Constitution imposes the requirement that "no person shall be held to answer for a capital or otherwise infamous crime unless on a presentment or indictment of a grand jury." It is elementary, of course, that there can be no conviction or punishment for a crime without a sufficient accusation; indeed, the court acquires no jurisdiction to try a defendant for a criminal offense unless he has been charged in the form and mode required by law. "If that is wanting, his trial and conviction is a nullity * * *" (*Weeks* v. *United States*, 216 Fed. 292, 293).

An infamous crime, within the contemplation of the Bill of Rights, is governed, not by the character of the crime, but rather by the nature of its punishment (*Weeks* v. *United States*, 216 Fed. 292). Generally, a crime punishable by imprisonment in a penitentiary is "infamous." Under current statutory provisions (18 U. S. C. 541), a crime punishable for more than one year, may be prosecuted *only* by indictment or presentment (*Falconi* v. *United States*, 280 Fed. 766), unless waived in open court by the defendant, after he has been advised of the nature of the charge and his rights (Rule 7 (b), *Rules of Criminal Procedure*). The record does not show such a waiver.

Appellant was prosecuted herein by information (R. 3-13, 19-41, 49-116).

Since the crimes with which he was charged clearly fall within the accepted definition of an "infamous offense," appellant has been deprived of his liberty and property without due process of law (*Weeks* v. *United States*, 216

Fed. 292). The penalty provisions of the statute read [21 U. S. C. 333 (a) and (b)]:

PENALTIES.

SEC. 303. (a) Any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * *

(b) *Notwithstanding the provisions of subsection (a) of this section, in case of violation of any of the provisions of Section 301, with intent to defraud or mislead,* the penalty shall be imprisonment for not more than *three years,* or a fine of not more than $10,000, or both such imprisonment and fine." (Italics supplied.)

Appellant was charged, in all informations, with "the introduction or delivery for introduction into interstate commerce of any food * * * that is * * * misbranded." There is only *one* such offense stated in the statute (21 U. S. C. 331 (a))—not *two*, one with, and one without intent to defraud or mislead (*Cf. United States* v. *Dotterweich*, 320 U. S. 277). The additional period of imprisonment (up to three years) is found, moreover, not in the "offense" section of the statute, but in the "penalties" section. In short, it goes to the *penalty* that the court *may* impose after hearing the evidence adduced and considering all facts in aggravation or mitigation of the offense.[26]

[26] The fact that the court did not actually impose a sentence in excess of one year is not material; it is the sentence that the court *may* impose, and not what it does impose, that determines whether the crime is an "infamous" one (*United States* v. *Moreland*, 258 U. S. 433; *De Jianne* v. *United States*, 282 Fed. 737 (C. C. A. 3, 1922)). Nor is it controlling that the statute designates violations as misdemeanors (*Ex parte Bredo*, 279 Fed. 147).

A reasonable construction of the statute demonstrates that appellant, on the charges brought against him, may have been penalized by imposition of a prison term in a penitentiary and in excess of one year. The crime must therefore be designated as an "infamous" one, requiring that he be prosecuted by presentment or indictment of a grand jury. Since this was lacking, his trial and conviction was a nullity (*Weeks* v. *United States*, 216 Fed. 292).

The circuit court of appeals evidently based its rejection of this argument on *United States* v. *Wells*, 186 Fed. 248, "holding violation of the 1906 Food and Drugs Act not an infamous crime" (R. 467). It is true that under the prior Act it had been held that offenses were not infamous, but could be brought on information. See, in addition, *Weeks* v. *United States*, 216 Fed. 292; *Frank* v. *United States*, 192 Fed. 864. It should be noted, however, that the maximum penalty thereunder, for a first offense, was a fine not exceeding $200; subsequent offenses could be penalized with a fine of $300, or less, or imprisonment not exceeding one year, or both. Section 2. Obviously, under no circumstances could violations be considered "infamous crimes."

It is not unreasonable or without precedent for the Congress to have left with the trial judge the right to impose alternate penalties for the same crime, depending on the manner of its commission, and to give to the court the right to impose the more severe penalties of section 303(b). Indeed, this merely follows the general tenor of the Act which similarly grants the Federal Security Administrator analogous powers in regard to "minor violations"—he may report them for prosecution, or not, as he deems fit (Section 306; *United States* v. *Sullivan*, 332 U. S. 689).

It further appears to be appellee's contention that before the more severe penalties of section 303(b) are imposable, appellant would have had to have been charged

with the intent to defraud or mislead. This argument is without foundation. In *Husty* v. *United States*, 282 U. S. 694, this Court had before it construction of the Jones Act amendment to the National Prohibition Act, where a like discretion in imposing sentence was involved. Its decision in that case serves as a complete answer to appellee (pp. 702-3):

> "It is urged that the indictment is defective, because it fails to state whether the offenses charged were felonies or misdemeanors, or whether the petitioners were charged with casual or slight violations of the law, which, petitioners argue, were made new or aggravated offenses by the Jones Act.
>
> "But the Jones Act created no new crime. It increased the penalties for 'illegal manufacture, sale, transportation, importation or exportation,' as defined by §1, title II of the National Prohibition Act, to a fine not exceeding $10,000, or imprisonment not exceeding five years, or both, and added as a proviso, 'that it is the intent of Congress that the court, in imposing sentence hereunder, should discriminate between casual or slight violations and habitual sales of intoxicating liquor, or attempts to commercialize violations of the law.' *As the Act added no new criminal offense to those enumerated and defined in the National Prohibition Act, it added nothing to the material allegations required to be set out in indictment for those offenses. The proviso is only a guide to the discretion of the court in imposing the increased sentences for those offenses for which an increased penalty is authorized by the Act.*" (Italics supplied.)

Moreover, it is clearly established that a court, in imposing sentence, is *not* confined to the evidence adduced at the trial, but may, where it has discretion to fix punish-

ment, consider other evidence as to matters which may be an *aggravation* or mitigation of the offense, although not admissible on the issue of guilt or innocence. *Hunter* v. *United States*, 149 F. 2d 710, 711, *cert. den.* 326 U. S. 787; Rule 32, Federal Rules of Criminal Procedure. It is also interesting to note that the form of information or indictment for food and drug violations suggested in the Federal Rules of Criminal Procedure (Form 11, Appendix of Forms) does not provide for the alternate allegation of "intent to defraud or mislead."

VIII.

THE CIRCUIT COURT ERRED IN ITS DEFINITION OF FALSE OR MISLEADING BRANDING.

Lacking any really serious charge either against the articles involved or the claims made on their behalf, the circuit court of appeals evolved a most curious—and inherently irresponsible—definition of the phrase " • • • false and misleading in any particular." It stated (R. 465-466):

> "Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger, however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. • • • Since the literature • • • em-

> bodies such misleading representations, it constitutes misbranding within the meaning of the Act."

In holding that misbranding takes place if "ignorant and gullible persons are likely to rely upon them instead of seeking professional advice" (R. 465) the circuit court of appeals was an unwitting victim of the outstanding argument of organized medicine against the use of all but a very few so-called "patent medicines." It is not unreasonable for physicians, as a group, to disparage and belittle self-medication; it is, however, wholly unreasonable for this Court or any other court to give sanction to this "trade argument" by its decision.

In simple logic, the rule thus promulgated by the circuit court spells the death-knell of *all* proprietary preparations —and indeed *all* self-medication. For using its test (R. 466), who is to say that a simple cough may not be symptomatic of cancer of the throat, that a laceration might not lead to septicemia, that a headache may not be the first sign of a brain injury? Since a large portion of the population eventually die of some fatal disease, medical witnesses can always solemnly propound the attitude they have so pompously announced during this trial. Under these circumstances, obviously *no* self-medication is "safe." Yet that is the effect of the ruling.

Why issue such a "blank check" to organized medicine? Is there any assurance of a cure or of perpetual life if one is attended by a physician? Is the practice of medicine of such perfection as to insure recovery from all human ills? Evidently, the circuit court of appeals for the fifth circuit in the *Urbeteit* decision (164 F. 2d 245, 248) did not think so when it so pertinently pointed out:

> "The most eminent physicians and scientists have in the past erred in their opinions * * *."

Certainly this Court should give serious consideration to a decision which contains so many radical and untenable innovations in the law and its application to food and drugs.

CONCLUSION

For all the above reasons, the judgment should be reversed, the case remanded, and the informations ordered dismissed.

Respectfully submitted,

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